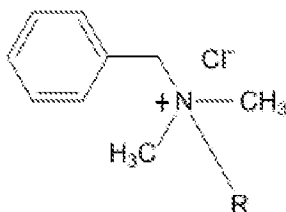


REMARKS

Claims 37-50, 52-53 and 55-73 are pending, wherein claims 37, 71 and 72 have been amended, claim 54 was cancelled, and new claim 73 was added. Reconsideration and allowance for the above-identified application are now respectfully requested.

The Office Action rejects claims 37-47 and 53-72 under 35 U.S.C. § 103(a) as being unpatentable over Squires (U.S. 6,355,684) and Remington's Pharmaceutical Sciences, 1975 (Remington Article). In response, Applicant has amended the claims in a manner that is believed to distinguish over the art of record.

Claim 37 as now amended claims a method for locally treating pathogen-induced disordered tissue caused by at least one of a virus, a bacteria, or a fungus, comprising applying a treatment composition to disordered tissue caused by a virus, bacteria or fungus so as to form a reservoir of the treatment composition within the disordered tissue and so that the treatment composition kills at least one of viruses, bacteria or fungus before diffusing beyond the disordered tissue and leaves no significant residue on a surface of the disordered tissue after penetrating into the disordered tissue (claim 54). The treatment composition is effective in killing at least of viruses, bacteria or fungus after only a single application of the treatment composition to the disordered tissue. The treatment composition comprises at least one organohalide compound in a liquid carrier that includes a tissue penetrating agent for penetrating skin and the disordered tissue and so that the treatment composition leaves no significant residue on a surface of the disordered tissue after penetrating into the disordered tissue (claim 54), the at least one organohalide compound comprising one or more of n-dialkyl methyl benzyl ammonium halide, n-alkyl dimethyl ethylbenzyl ammonium halide, a quaternary ammonium halide having an ammonium nitrogen and an alkyl radical with six to eighteen carbons bonded to the ammonium nitrogen, or benzalkonium chloride having the following chemical structure:



wherein R is an alkyl group having 8-18 carbons. Because claim 37 is claim 54 rewritten in independent form, a subsequent office action that rejects claim 37 on a new ground of rejection must be non-final.

Applicant submits that claim 37 claims a combination of elements that is neither taught nor suggested by the applied art. For example, claim 37 as amended claims, in combination with the other recited elements, a method in which the treatment composition, when used as claimed, kills at least one of viruses, bacteria or fungus before diffusing beyond the disordered tissue and leaves no significant residue on a surface of the disordered tissue after penetrating into the disordered tissue. The treatment composition penetrates into the disordered tissue rather than remaining on the surface and is therefore located within the disordered tissue where it can perform the desired treatment action of killing viruses, bacteria or fungus. Because the treatment composition is completely absorbed into the disordered tissue and does not remain on the surface of the disordered tissue it cannot be washed off and become deactivated. This mitigates against inadvertent deactivation of the treatment composition during treatment by a user who happens to wash the treatment area, as occurs when using the composition of Squires.

Squires, by contrast, fails to teach or suggest the claimed methods because it specifically teaches a composition that is designed to form a coating on the surface of the treated area during the course of treatment. The “microbicide solution provides a moderately *water resistant coating* upon application to either the prodromal tissue or the erythematous vesicular herpes lesion”. Col. 2, ll. 56-58 (emphasis added). “The *coating* of the solution (medicine) *should be maintained until all external symptoms completely resolve*, reapplying as needed anytime the coating diminishes, for instance, after showering. Anionic soaps and anionic detergents, and especially protein content soaps [that remove the coating] can be contraindicated. Col. 6, ll. 60-65 (emphasis added). Maintaining the treatment area “well coated” was required to effectively treat the infected tissue. See col. 10, ll. 53-62. According to Squires, prematurely washing the coating off the affected area compromised the ability of the Squires composition to effectively treat the infected tissue, which caused a flair up of the skin condition and required reapplication of the composition to treat the skin condition:

One human male subject reported that after the initial application during the prodrome phase of an outbreak, he showered and forgot to reapply the composition (medicine) for a period of approximately 30 hours. *Consequently, several vesicles erupted and began to coalesce*. The subject proceeded to reapply the composition (medicine) and thereafter kept the area well coated with the composition. Subsequently, the outbreak resolved in 21 hours in the same manner as described with the other human subjects

Col. 10, ll. 53-62 (emphasis added). In view of the foregoing, Applicant submits that Squires fails to teach or suggest a method of treating disordered tissue in which the treatment composition “kills at least one of viruses, bacteria or fungus before diffusing beyond the disordered tissue and leaves no significant residue on a surface of the disordered tissue after penetrating into the disordered tissue”. And in fact, Squires teaches the exact opposite: a coating of the treatment composition must remain on the surface of the treated tissue “until all external symptoms completely resolve”. Failure to do this will cause an outbreak and require reapplication of the treatment composition. *See* col. 10, ll. 53-62. Accordingly, for this reason alone, Applicant submits that claim 37 is patentable over Squires.

The Remington Article does not and cannot cure the deficiencies of Squires without undermining the “principle of operation” of the treatment composition and method disclosed in Squires, which requires the treatment composition to remain coated on the treated area during treatment to be effective. In view of this, Applicant submits that, even if one were to combine Squires and the Remington Article, the combined teachings neither teach nor suggest the combination of elements recited in claim 37 as amended.

Claims 38-50, 52-43 and 55-70 depend from claim 37 and are therefore patentable for at least the reasons given above relative to claim 37. In addition, they recite additional elements that further distinguish over the art of record. For example, claim 38 claims a method in which the treatment composition is applied to the disordered tissue so as to penetrate through the stratum corneum and form the reservoir of treatment composition within the stratum spinosum of the disordered tissue. The combination of Squires and the Remington Article neither teaches nor suggests this method of operation. The Office Action acknowledges that the cited art fails to teach or suggest any such method, but alleges that it may be an inherent feature of the composition of Squires and shifts the burden to Applicant to prove otherwise. In response, Applicant notes that Squires teaches that the composition forms a coating on the surface of the treated area while teaching nothing with respect to the ability of the composition to penetrate into and through the disordered tissue so as to form a reservoir of the composition in the manner recited in claim 38. Moreover, Applicant submits that because washing the treated area deactivates the Squires composition, that is strong evidence that the Squires composition is not able to penetrate through the stratum corneum and form the reservoir of treatment composition within the stratum spinosum of the disordered tissue. More fundamentally, Applicant notes that the Application clearly teaches that the ability of a treatment composition to penetrate below the

skin surface is not only a function of what the composition contains but also what it does not contain. Compositions, such as those described in Beauchamp, may contain very large quantities of tissue penetration inhibiting components that offset the ability of a composition to otherwise penetrate through the tissue in the absence of the tissue penetration inhibiting components. Therefore, Applicant has rebutted the allegation of inherency, thereby shifting the burden back to the Examiner to show that the composition of Squires does in fact penetrate and form a reservoir of composition in the manner recited in claim 38.

Claim 41 claims a method in which the treatment composition is applied to the disordered tissue while compressing the disordered tissue. Claim 42 claims specific aspects of compressing disordered tissue. Neither Squires nor the Remington Article teaches or suggests any such method. The application teaches that compressing the disordered tissue rather than rubbing it onto the surface can increase the ability of the composition to penetrate through and into the disordered tissue while minimizing the risk of tearing or damaging the disordered tissue.

Claim 53 further modifies what is meant in claim 37 that the composition “leaves no significant residue on a surface of the disordered tissue after penetrating into the disordered tissue”. The Office Action alleges that this is an inherent feature of the Squires composition. However, Applicant has quoted several passages from Squires that shows that a feature of the Squires composition is the propensity of the composition to form a *coating* on a surface of the treatment tissue throughout treatment until symptoms subside. That is why the patient in Squires who took a shower and washed off the treatment composition and forgot to reapply the composition after showering suffered a recurrence and flair up of the skin condition. Col. 10, ll. 53-62. In sharp contrast, the ability of the composition of the claimed method to penetrate through the tissue and “leave[] no significant residue on a surface of the disordered tissue after penetrating into the disordered tissue” mitigates the problems inherent in the Squires composition in which prematurely washing off the composition deactivates it, undermines its effectiveness, and results in a flair up of the skin condition. Therefore, the Applicant has rebutted the charge of inherency and has shifted the burden back to the Examiner to show where Squires teaches or suggests a composition that “leaves no significant residue on a surface of the disordered tissue after penetrating into the disordered tissue” and which therefore cannot be washed off the skin surface and deactivated as taught in the Squires example.

The remaining independent claims are patentable over Squires and the Remington Article for similar reasons set forth above relative to claims 37 and/or 53 and/or 42.

In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by Examiner amendment, the Examiner is requested to contact the undersigned attorney.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account No. 23-3178**: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178**.

Dated this 13th day of September 2010.

Respectfully submitted,

/John M. Guynn 36153/

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